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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,407	12/26/2001	Larry Caldwell	CALD-007	3764

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/029,407	CALDWELL ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged applicants' amendment and request for RCE, both filed 12/27/2006; and declaration filed 01/05/2006.

Claims 24-26 have been added.

Claims 1-26 are pending and included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/27/2005 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification has not described the topical formulations for delivering NSAID with regard to doses of drug, other non-active ingredients in the formulation such as carriers, and enhancers. The specification failed to describe how the formulation was done and how the formulation will deliver NSAID to the site of pain without other ingredients that carry the drug or facilitate its transport across the stratum cornium. The specification failed to define the claimed patch or its structure that delivers NSAID topically and not systemically. The specification failed to describe topical NSAID formulation "consisting of" or "consisting essentially of" NSAID.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 2, 5-7, 10, 11, 24-26 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,416,772 ('772).

US '772 discloses composition for transdermal pain relief such that patient can apply an analgesic agent directly topically to an area of pain and effective to relief headaches (abstract; col.3, line 61). In a preferred embodiment, acetaminophen or naprosyn are used, i.e. NSAID (col.3, lines 1-2).

6. Claims 1-13, 16, 19-26 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2002/0143047 ('047).

The applied reference has one common inventor and a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

US '047 discloses method and composition and kit for treating headache in human or mammals wherein the method comprising topical application of indomethacin formulation to a keratinized skin site proximal to the pain such as forehead or temple (abstract; paragraph 0025). The headache can be exertional headache, i.e. tension headache (paragraph 0015). The formulation can be cream or patch (paragraph 0016). The kit comprises instructions for using the formulation (paragraph 0026, 0027).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 2, 5-7, 10, 11, 14-18, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,416,772 ('772) combined with US 5,318,960 ('960).

US '772 teaches composition for transdermal pain relief such that patient can apply an analgesic agent directly topically to an area of pain and effective to relief headaches (abstract; col.3, line 61). In a preferred embodiment, acetaminophen or naprosyn is used (col.3, lines 1-2).

US '772 does not explicitly teach the claimed types of headache, the specific NSAID.

It is expected that NSAIDs disclosed by US '772 are able to treat any kind of headache such as tension headache, sinus headache, cluster headache or migraine headache.

US '960 teaches composition for pain relief comprising NSAIDs that when applied to the skin of the patient will deliver pain relieving substance directly to the afflicted area of the body, thus alleviating the side effects caused by systemic application and allowing NSAID to be delivered precisely to the body at specific area of pain (abstract; col.2, lines 5-9, 61-65). Examples of NSAID include indomethacin, ketoprofen, diclofenac, and ibuprofen (col.3, lines 50, 53, 56; col.6, lines 30, 58).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat headache by topically applying at the site of pain composition comprising NSAID as disclosed by US '772, and replace the acetaminophen or naprosyn by any of indomethacin, ketoprofen, diclofenac, and ibuprofen disclosed by US '960, motivated by the teaching of US '960 that these specific NSAID are preferred for topical application to relieve pain at specific area of the body without causing systemic side effects, with reasonable expectation of having topical formulation comprising one of indomethacin, ketoprofen, diclofenac, and ibuprofen that is able to relive headache with great success when applied topically to the site of pain, i.e. forehead or temporal area.

10. Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,416,772 ('772) combined with US 5,725,874 ('874).

US '772 teaches composition for transdermal pain relief such that patient can apply an analgesic agent directly topically to an area of pain and effective to relief headaches (abstract; col.3, line 61). In a preferred embodiment, acetaminophen or naprosyn is used (col.3, lines 1-2).

US '772 does not explicitly teach the claimed types of headache, the specific NSAID claimed in claims 14-18, the cream and patch as claimed in claims 3, 4, 8, 9, 12, 13, 21, and 22, and the kit of claim 19-23.

It is expected that NSAIDs disclosed by US '772 are able to treat any kind of headache such as tension headache, sinus headache, cluster headache or migraine headache.

It is known in the pharmaceutical art to include written instruction with the medications instructing the patient on how to use the medicine to avoid any undesirable side effects.

US '874 teaches percutaneously absorbable formulation that is extremely safe and causes little side effects wherein the formulation can be in the form of cream of patch to deliver NSAID such as of indomethacin, ketoprofen, diclofenac, and ibuprofen (abstract; col.2, lines 61-62; col.3, lines 35-37).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat headache by topically applying at the site of pain composition comprising NSAID as disclosed by US '772, and replace the

acetaminophen or naprosyn by any of indomethacin, ketoprofen, diclofenac, and ibuprofen in the form of cream or patch as disclosed by US '874, motivated by the teaching of US '874 that cream or patch comprising NSAID are extremely safe and cause little side effects, with reasonable expectation of having extremely safe cream or patch comprising one of indomethacin, ketoprofen, diclofenac, and ibuprofen that is able to relive headache with great success when applied topically to the site of pain, i.e. forehead or temporal area, with minimal side effects.

11. Claims 14, 15, 17, and 18 are rejected under 35 U.S.C. 103(a) as being obvious over US 2002/0143047 ('047) in view of US 5,318,960 ('960).

The applied reference has a common assignee and one common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection

might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

US '047 teaches method and composition and kit for treating headache in human or mammals wherein the method comprising topical application of indomethacin formulation to a keratinized skin site proximal to the pain such as forehead or temple (abstract; paragraph 0025). The headache can be exertional headache, i.e. tension headache (paragraph 0015). The formulation can be cream or patch (paragraph 0016). The kit comprises instructions for using the formulation (paragraph 0026, 0027).

US '047 does not teach specific NSAID claimed in claims 14, 15, 17 and 18.

US '960 teaches composition for pain relief comprising NSAIDs that when applied to the skin of the patient will deliver pain relieving substance directly to the afflicted area of the body, thus alleviating the side effects caused by systemic application and allowing NSAID to be delivered precisely to the body at specific area of pain (abstract; col.2, lines 5-9, 61-65). Examples of NSAID include indomethacin, ketoprofen, diclofenac, and ibuprofen (col.3, lines 50, 53, 56; col.6, lines 30, 58).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat headache by topically applying at the site of pain composition comprising NSAID as disclosed by US '047, and replace the indomethacin by any of indomethacin, ketoprofen, diclofenac, and ibuprofen disclosed by US '960, motivated by the teaching of US '960 that these specific NSAID are preferred for topical application to relieve pain at specific area of the body without causing systemic side

effects, with reasonable expectation of having topical formulation comprising one of indomethacin, ketoprofen, diclofenac, and ibuprofen that is able to relive headache with great success when applied topically to the site of pain.

Response to Arguments

12. Applicant's arguments with respect to claims 1-23 have been considered but are moot in view of the new ground(s) of rejection.

Response to Amendment

13. The declaration under 37 CFR 1.132 filed 01/05/2006 has been considered but is moot in view of the new ground(s) of rejection.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

IG

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